AUG 1 4 2000

SUMMARY OF SAFETY AND EFFECTIVENESS

K001270

1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Millennium 9000 Phased Array Neurovascular Coil
3. Classification :	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Neurovascular Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the brain, cervical spine, soft tissues and vasculature of the head, neck and upper chest extending to the cardiac region in Magnetic Resonance Imaging Systems. The Millennium 9000 Neurovascular Coil is designed for use with the Excel Art™ 1.5T MRI systems manufactured by Toshiba Medical Systems, Inc. The indications for use are the same as for standard MR Imaging.
8. Device Description:	The Millennium 9000 Phased Array Neurovascular Coil is an 8-element quadrature phased array, receive-only coil. The coil consists of three sections: a main coil base, a sliding open designed head former, and a detachable chest plate. The split-top, sliding design minimizes claustrophobic effects and maximizes patient comfort. The coil elements and accessory electronics are enclosed in a rigid plastic housing, which is fire rated and has a high impact and tensile strength.

Please turn over

9. Safety and Effectiveness

Millennium 9000 Phased Array Neurovascular Coil product features	Comparison to predicate device or other 510(k) cleared products
Intended Use: Imaging of the brain, cervical spine, soft tissues and vasculature of the head, neck, and upper chest	-Similar to the Medrad Phased Array Neurovascular Coil manufactured by Medrad, Inc.(K984257)
Indications for Use: Identical to routine MRI imaging	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157)
Coil Enclosure Material: Hapco 304/305 Liquid molding compound Hapco 912 Liquid molding compound Innovative Polymers RC-79 Vinyl Coated PVC Foam Delrin AF Acetal	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157) -Similar to the Magna 5000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K994345 & K000002) -Similar to the Liberty 9000 Breast Coil manufactured by USA Instruments, Inc. (K000993)
Coil Design: Receive-only phased array coil	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157)
Decoupling: Switching diode decoupling	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157)
Prevention of RF Burns: Does not transmit RF power; decoupling isolates the coil elements from RF fields during RF transmission; coil elements and circuitry are enclosed in a non-conductive housing.	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157)
Radio Frequency Absorption: Coil is a receive only coil and does not transmit RF power.	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157)
Formation of Resonant Loop: Decoupling isolates the coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping	- Similar to the Premier 7000 Phased Array CTL Spine Coil manufactured by USA Instruments, Inc.(K980157)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2000

Tori Bruns
Regulatory Specialist
USA Instruments, Inc.
1515 Danner Drive
Aurora, Ohio 44202

Re: K001870
Millennium 9000 Phased Array Neurovascular Coil
Dated: June 16, 2000
Received: June 20, 2000
Regulatory Class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Ms. Bruns:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): K001870

Device Name: Millennium 9000 Phased Array Neurovascular Coil

Indications for Use: The Millennium 9000 Phased Array Neurovascular Coil is designed to provide Magnetic Resonance Images of the brain, cervical spine, soft tissues and vasculature of the head, neck and upper chest. The Millennium 9000 Phased Array Neurovascular Coil is designed for use with the Excel Art™ 1.5T scanner manufactured by Toshiba Medical Systems.

Anatomic Regions: Soft tissues and vasculature of the head, neck and upper chest.
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The 1.5T MRI system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001870